

REMARKS

This Amendment, filed in reply to the Office Action dated May 1, 2008, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 11-14 and 25-36 are all the claims pending in this application. Claim 36 is withdrawn from consideration. Claims 11-14 and 25-35 are rejected.

Claims 11, 12, 30-33 and 35 are amended herewith. Claim 11 is amended herewith to recite that the sterile microorganism growth substrate comprises a biomass generated from bacterial cells by autolysis, optionally followed by ultrafiltration and evaporation, wherein said bacterial cells comprise *Methylococcus capsulatus* (Bath) (strain NCIMB 41526), *Ralstonia* sp. DB3 (strain NCIMB 41527), *Aneurinibacillus* sp. DB4 (strain NCIMB 41528) and *Brevibacillus agri* DB5 (strain NCIMB 41525). Support for this amendment can be found throughout the specification as filed, and at, for example, the paragraph bridging pages 5 and 6.

New Claim 37 is introduced, which recites that the sterile microorganism growth substrate comprises a biomass generated from bacterial cells "by autolysis followed by ultrafiltration and evaporation." Support for this amendment can be also found throughout the specification as filed, and at, for example, the paragraph bridging pages 5 and 6.

Claims 12, 30, 31 and 35 are amended herewith to depend from either Claim 11 or Claim 37. Claims 28, 29, 34 and 36 are canceled herewith without prejudice or disclaimer. No new matter is added by way of this amendment. Entry and consideration of this amendment are respectfully requested.

The Rejection of Claims 28 and 29 under 35 U.S.C. § 112, first paragraph, is Moot

On page 3 of the Office Action, the Examiner maintains the rejection of Claims 28 and 29 under 35 U.S.C. 112, first paragraph, as lacking enablement for the deposited microorganisms.

Regarding the Statement of Availability previously submitted by Applicants, the Examiner asserts that the strains listed therein do not correspond to those claimed, or those recited in the specification. Further, the Examiner asserts that the previous response did not recite a basis for a change in deposit number.

Initially, Applicants note that Claims 28 and 29 are canceled herewith, mooted the rejection. Nevertheless, in the interest of advancing prosecution, Applicants address the rejection as it applies to the instant claims as amended.

In response, Applicants note that a biological deposit was made for the claimed microorganisms as indicated by the deposit numbers for each organism at page 3, 2nd paragraph, and Example 1, in the paragraph bridging pages 5 and page 6, of the specification as filed. Applicants note that these deposited microorganisms are publicly available and deposited with NCIMB¹ (National Collection of Industrial and Marine Bacteria Ltd.). However, because the initial deposits were not made under the conditions of the Budapest Treaty, Applicants also

¹ NCIMB is a professional microbiology company that has built and managed the largest industrial, marine and food culture collection in the UK since the 1950s, and has provided commercial microbiology services to multiple companies in diverse industries since 1983. In addition, NCIMB has held the status of International Depositary Authority under the Budapest Treaty since 1982, and that any organism deposited under the Treaty with culture collections meets the deposit requirements of patent offices in all countries party to the Treaty.

deposited the *same* strains, at the *same* depository, but under the conditions of the Budapest Treaty.² Applicants note that although the deposits were assigned new deposit numbers by the depository, the deposited strains are the *same* as those initially deposited, and identified in the specification, as is clear from the nomenclature of each specific strain, which is identical in both deposits. Accordingly, the replacement deposits meet all the requirements for making an original deposit pursuant to 37 C.F.R. 1.805

In addition, and pursuant to M.P.E.P. § 2406.01 and 37 C.F.R. § 1.804(a), Applicants have amended the specification herewith to include information designating the depository, accession number, and deposit date of each of the claimed microorganisms.

Withdrawal of the rejection is respectfully requested.

Claims 11-14, 25-27 and 30-35 are Patentable Under 35 U.S.C. § 103

On page 5 of the Office Action, the Examiner maintains the rejection of Claims 11-14 and 25-35 under 35 U.S.C. 103(a) as being unpatentable over Bothe *et al.*, taken with Norferm, DA, Larsen & Joergensen, Atlas & Parks and Patz *et al.*, essentially for reasons of record.

In response to Applicants' previous arguments, the Examiner asserts that Bothe *et al.*, in combination with the Norferm DA brochure and Atlas & Parks, provide detailed disclosure as to how to prepare a protein-rich biomass from methanotrophic bacteria, which can be combined

² Pursuant to 37 C.F.R. § 1.805(f) and M.P.E.P. § 2407.04, an applicant for patent may make a replacement deposit during the pendency of the application for any reason.

with sterile nutrients, and sterilized, as disclosed by Atlas & Parks in order to prepare a sterile growth medium or substrate as claimed.

Regarding Patz *et al.*, the Examiner asserts that Patz *et al.* provide a “realization” to one of ordinary skill in the art that a biomass from a methanotrophic microorganism is suitable as a microbial growth substrate, citing page 5. The Examiner also purports that the disclosure in the Norferm DA brochure that administration of a bacterial biomass to *humans and animals*, such as pigs and fish, “clearly implicate[s] the suitability of said biomass as a growth substrate for various microorganisms, for example, intestinal microbes that reside in animal gut.”

The Examiner also takes the position that a biomass rich in protein “would be deemed naturally obvious by an artisan of ordinary skill in the microbial art for its use as ... a suitable microbial growth substrate” and that it is “common knowledge in the microbial art that an organic biomass (sterile or not) is generally deemed to be a good source of protein, carbon, nitrogen, and other chemical micronutrients upon which several species of microbes would readily grow, if appropriate conditions for growth are provided.”

Regarding the suitability of the claimed composition as a “broad spectrum growth medium,” the Examiner states that such a property is “neither required by the limitations of the claims as currently presented, nor fully demonstrated by Applicants in the instant disclosure as originally filed with the office,” citing Table 1, page 8.

Applicants respectfully disagree, and traverse the rejection on the following grounds.

Initially, Applicants note that the nutritional needs of different bacterial species differ remarkably, and for this reason, it would not have been obvious to one of skill in the art whether

a biomass generated from methanotrophic and heterotrophic bacteria would be suitable as a “broad-spectrum” growth substrate for microorganisms. Indeed, although Patz *et al.* is relied upon to support the rejection, Patz *et al.* only disclose a biomass produced from *Methylobacterium rhodesianum* IMET 11401 as a substrate for growth of the *very same* bacterial strain. Further, regarding the Examiner’s contention that the weight gain achieved in animals fed the Norferm biomass “clearly implicate[s] the suitability of said biomass as a growth substrate for various microorganisms, for example, intestinal microbes that reside in animal gut,” Applicants note that the animals in which weight gain was measured do not derive any substantial nutrition from gut flora, unlike ruminants, and thus one of ordinary skill in the pertinent art would clearly not consider such animal weight gain to be any indicator of suitability as a microbial growth medium.

While Applicants believe that for these reasons alone, one of ordinary skill in the art would not consider that a biomass generated from methanotrophic and heterotrophic bacteria would be suitable as a “broad-spectrum” growth substrate for microorganisms, in the interest of advancing prosecution, and without acquiescing in the rejection, Applicants herewith amend Claim 11 to recite that the claimed biomass is a sterilized nutrient composition, wherein said composition is a biomass generated from bacterial cells by autolysis, optionally followed by ultrafiltration and evaporation, wherein said bacterial cells comprise *Methylococcus capsulatus* (Bath) (strain NCIMB 41526), *Ralstonia* sp. DB3 (strain NCIMB 41527), *Aneurinibacillus* sp. DB4 (strain NCIMB 41528) and *Brevibacillus agri* DB5 (strain NCIMB 41525).

As discussed in the paragraph bridging pages 5 and 6 of the specification as filed, Applicants experimentally demonstrate production of a biomass by autolysis of *Methylococcus capsulatus* (Bath) (strain NCIMB 41526), *Ralstonia* sp. DB3 (strain NCIMB 41527), *Aneurinibacillus* sp. DB4 (strain NCIMB 41528) and *Brevibacillus agri* DB5 (strain NCIMB 41525), which is termed “BP Autolysate,” and production of a biomass produced by subjecting the “BP Autolysate” to ultrafiltration and evaporation, which is termed a “BP Extract.”

As discussed in Example 2 in the specification as filed, growth media were produced using the “BP Autolysate” and “BP Extract” biomasses. As shown in Table 1 on page 8 of the specification as filed, the growth media containing the “BP Autolysate” and “BP Extract” biomasses allowed superior growth of exemplary gram-positive, gram-negative, aerobic and anaerobic bacteria when compared to the control growth media, for the majority of the bacteria tested. Applicants note that the control growth substrates used in the experiments depicted in Table 1 were not “broad-spectrum” growth substrates, but were in fact growth substrates recognized to be specifically suitable for growing the particular species of bacteria tested.

Thus, even assuming *arguendo* that one of ordinary skill in the art would consider using a biomass generated from methanotrophic and heterotrophic bacteria as a sterile microorganism growth substrate, nothing in the art would lead one of ordinary skill in the art to expect that the claimed growth substrate would allow superior growth of even a *single* species of microorganism vis-a-vis the non-broad spectrum control growth substrate, which as discussed above, is recognized in the art as being specifically suitable for growing that particular microorganism. Accordingly, it would have been entirely unexpected that the claimed growth substrate would

allow superior growth across a broad-spectrum of different bacteria, *i.e.*, gram-positive, gram-negative, aerobic and anaerobic bacteria, when compared to the respective non broad-spectrum control growth substrate, wherein each control substrate is recognized in the art as being specifically suitable for growing the particular microorganisms tested. That Applicants' claimed growth substrates are superior to even the control substrates for the majority of the bacteria tested could not have been expected, and is further probative of the non-obviousness of the claimed invention.

Accordingly, Applicants respectfully submit that the claims as amended are not rendered obvious over the cited references at least in view of the superior growth obtained with a broad-spectrum of bacteria, *i.e.*, gram-positive, gram-negative, aerobic and anaerobic bacteria, on the claimed substrates, even when compared to non broad-spectrum control growth substrates, each control substrate being recognized in the art as being specifically suitable for growing the particular microorganism tested. Clearly, such superior growth properties could not have been expected by one of ordinary skill in the pertinent art, and as such, would not have been obvious.

Withdrawal of this rejection is respectfully requested.

Obviousness-Type Double Patenting

1. On page 14 of the Office Action, the Examiner provisionally rejects Claims 11-14 and 25-35 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 30, 32-35, 37-42 and 44 of copending Application No. 10/504,464.

2. On page 15 of the Office Action, the Examiner *provisionally* rejects Claims 11-14 and 25-35 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 8, 13-25 and 27 of copending Application No. 10/504,463

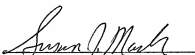
Because these rejections are merely provisional in nature, Applicants kindly request that they be held in abeyance until such time as allowable subject matter is identified.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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